**Title:** InTraocular EMulsion of Silicone oil (ITEMS) grading system: an evidence-based expert-led consensus.

**Short title:** Assessment ofsilicone oil emulsion

Mario R Romano, MD PhD1,2, Mariantonia Ferrara, MD3, Rosa M Coco-Martin, MD PhD4,5,6, Annekatrin Rickmann, MD7, Martin S Spitzer, MD8, David HW Steel, MD FRCOphth9,10, J Carlos Pastor, MD PhD4,5,6

1 Department of Biomedical Sciences, Humanitas University, Pieve Emanuele - Milano, Italy;

2 Eye Center, Humanitas Gavazzeni-Castelli, Bergamo, Italy;

3 Manchester Royal Eye Hospital, Manchester, United Kingdom;

4 Retina Group, Instituto Universitario de Oftalmobiología Aplicada (IOBA), Universidad de Valladolid, Campus Miguel Delibes, Paseo de Belén, 17, 47011, Valladolid, Spain;

5 Centro en Red de Medicina Regenerativa y Terapia Celular de Castilla Y León, Valladolid, Spain;

6 RICORS de enfermedades inflamatorias, Carlos III National Institute of Health, Madrid, Spain;

7 Eye Clinic Sulzbach, Knappschaft Hospital Saar, Sulzbach/Saar, Germany;

8 University Medical Center Hamburg-Eppendorf, Departrment of Ophthalmology, University of Hamburg, Hamburg, Germany;

9 Sunderland Eye Infirmary, Sunderland, United Kingdom;

10 BioscienceInstitute, Newcastle University, Newcastle Upon Tyne, United Kingdom.

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Corresponding author

Mario R Romano, MD, PhD,

Biomedical Sciences, Humanitas University,

Via Rita Levi Montalcini 4, 20090 Pieve Emanuele - Milano, Italy

email: mario.romano.md@gmail.com

**Keywords**: grading; silicone oil; silicone oil emulsion; silicone oil microbubbles; silicone oil-associated hyperreflective dots.

**Summary statement**: In absence of an agreement on the assessment of silicone oil emulsion, we propose an evidence-based grading system for silicone oil emulsion, allowing, for the first time, a homogenous assessment applicable in a clinical setting and, potentially, a better understanding of the role and clinical relevance of this dreaded complication.

**Abstract**

Purpose: To propose the InTraocular EMulsion of Silicone oil (ITEMS) grading system for the assessment of silicone oil (SiO) emulsion, applicable in a routine clinical setting and validated through an expert-led consensus procedure.

Methods: Seven experts on intraocular liquid tamponades, led by a facilitator, performed a literature review on the detection of SiO emulsion. Based on the proposed ideas, a questionnaire was developed and submitted to the experts on the methods to detect SiO emulsion and the items to grade. After two rounds of individual ranking using a nine-point scale and related discussion, the final grading system was developed including items that reached consensus (score ≥7 from ≥75% of members).

Results: The agreed ITEMS grading system includes the quantification of SiO microbubbles and large SiO bubbles through slit lamp biomicroscopy, gonioscopy, fundus examination under mydriasis or ultra-widefield fundus photography. Moreover, macular and disc OCT are used to detect SiO-associated hyperreflective dots.

Conclusion: An evidence-based expert-led consensus was conducted to develop grading system of SiO emulsion, allowing, for the first time, homogenous collection of data on SiO emulsion. This has the potential to improve our understanding of the role and clinical relevance of SiO emulsion allowing comparisons between different studies.

**Introduction**

Silicone oil (SiO) emulsion is an established and important complication associated with SiO tamponade. It has been speculated that SiO emulsification plays a crucial pathogenetic role in the majority of the potentially severe SiO-related complications, including intraocular inflammation, increased intraocular pressure and glaucoma, keratopathy, epiretinal membranes and optic neuropathy.1 This hypothesis is based on the ability of emulsified SiO droplets to penetrate into the ocular tissues, and their detection within various structures in both anterior and posterior segment, including the cornea, trabecular meshwork, ciliary body, retina and optic nerve.2,3

A previous experimental study, in the attempt to quantify and characterize SiO emulsion analyzing aqueous washouts after SiO removal with a Coulter counter Multisizer® 4 on, demonstrated that emulsified SiO droplets vary significantly in size, from microbubbles of < 2 μm, not detectable via slit-lamp examination, to larger droplets that can be easily observed through both clinical examination and ophthalmic imaging.3 Although this method is clearly not applicable in the clinical practice, the conclusions of this study are clinically relevant. Indeed, even if SiO droplets of < 2-μm diameter may represent the major component of SiO emulsion, it has been shown that their number positively correlates with that of larger SiO droplets.3 It follows that the evaluation of clinically detectable SO droplets represents a valid parameter to assess intraocular SiO emulsion.3

Despite the wide agreement regarding the primary role of SiO emulsification in SiO-related complications, available studies as well as potential reviews and meta-analyses cannot support any definite conclusions regarding the clinical relevance of SiO emulsion and its relationship with the physical characteristics of the different commercially available SO due to various significant limitations. These include the absence of definitive agreement on how to evaluate and grade SiO emulsion as well as unspecified high heterogeneity in terms of sample size, lack of uniformity in the systems used for identification and evaluation, and limited information regarding the type of SiO used.4,5 Zhao et al (REF) recently proposed the use of ultrasound biomicroscopy to garde SiO emulsion in the anterior chamber (AC); however, the applicability of their proposal has two crucial limitations, namely the use of a technology not easily accessible in the daily clinic, and the investigation of the AC only. This further highlights the lack of a clinical grading system.

In light of this background, our aim has been to propose the InTraocular EMulsion of Silicone oil (ITEMS) grading system for the assessment of SiO emulsion, applicable in a daily clinical setting and validated through a consensus procedure, which would contribute to improving our knowledge of the real role of emulsion in the development of ocular complications following the use of SiO. Indeed, the introduction and application of a protocolized grading system has the potential to provide, for the first time, a comparable classification of the severity of SO emulsion and, thus, allowing the reliable comparison and evaluation of the results of clinical studies.

**Methods**

The consensus was conducted using the nominal group or expert panel technique.6

A group of seven experts on intraocular liquid tamponades, from four different countries (Spain, Italy, United Kingdom and Germany) was formed and led by a facilitator (MRR) with the aim to develop an evidence- and consensus-based grading system of SiO emulsion. The criteria for the selection of experts were having specific publications, considerable clinical experience, recognition and willingness to participate in the project.6

After an initial discussion to identify the main methods of detection of SiO emulsion in a clinical setting, group members conducted literature reviews on several clinical findings of SiO emulsion and, based on these reviews, sent a summary documents and ideas on a grading system to provide a comprehensive quantification of intraocular SiO qmulsion, to the facilitator.

The facilitator merged all the documents and developed a questionnaire including all the proposed ideas (Supplementary Table 1). The questionnaire was circulated via email and each group member ranked all items on a 9-point scale for clinical utility and importance privately and sent it back to the facilitator.

The ranking was tabulated and a virtual meeting was arranged to discuss the results. Items for which a consensus was obtained (≥75% of members scoring between 7 and 9 inclusive) were briefly reviewed. Items where an agreement was not reached (≥75% of members scored it between 4 and 6 inclusive) were discussed and presented for the second round if agreement was reached during the discussion. Items scoring between 1 to 3 by ≥75% of members were excluded and not further discussed.

Based on the outcomes of the virtual meeting, the facilitator circulated via email a proposal of grading in which each item was re-ranked. A second virtual meeting was arranged to discuss the results of the re-ranking and the final ITEMS grading system was prepared.

**Results**

The design of the consensus protocol is shown in Figure 1, whereas the final ITEMS Grading System is shown in Table 1. The grading system can be used to grade all types of available conventional SiOs, mixtures of SiOs and very-high-molecular-weight components, and heavy SiOs (HSiOs), and other sources of SiO emulsion such as repeated injections of anti-angiogenic in non-pre-filled systems.

*Slit Lamp Examination of Anterior Segment*

The absolute consensus was achieved (100% of the expert group scored 9) to include the examination of the anterior segment through the slit lamp biomicroscopy. In particular, after the two rounds of discussion, consensus was reached on the following specific parameters to grade:

- Number of SiO emulsified microbubbles (<200 μm) into the anterior chamber (AC), using a scoring system similar to that used for the evaluation of AC cells proposed by the Standardization of Uveitis Nomenclature (SUN) Group.[7] Due to their different densities, emulsified droplets of conventional SiO and HSiO tend to accumulate in the superior and inferior part of the AC, respectively. Based on this behavior, it was recommended to measure the quantity of emulsified microbubbles in the upper third of AC in case of conventional SiO and lower third in case of HSiO.

- Presence of large (>200 μm) SiO bubble(s) into the AC. The cut-off of 200 μm was defined based on the smallest size of the slit measurable on the slit lamps.

- Presence and height (in mm) of a hyper- or hypo-oleon present, also called “creaming”. The hyper/hypo-oleon consists of the accumulation of emulsified SiO microbubbles, stabilized by biosurfactants, and appears as a whitish horizontal fluid level in the AC. Based on physical properties, the level will settle in the superior part of the AC (hyper-oleon) in case of conventional SiO and in the inferior part (hypo-oleon) in case of HSO. Similar to the clinical evaluation of a hypopyon, it was recommended to quantify the hyper/hypo-oleon measuruing the vertical height in mm.

*Gonioscopy*

All the experts agreed on the need to include gonioscopy in the grading system (100% of the expert scored 9). Consistent with the grading of SiO emulsion in the AC, it was recommended to separately grade the extent of SiO microbubbles detectable in the iridocorneal angle and the presence/absence of larger SiO bubbles.

*Dilated fundus examination or ultrawide-field fundus photography*

There was an absolute consensus on the need to include the dilated funduscopic examination in the grading system. The expert groups agreed unanimously to consider the ultrawide-field fundus photography, centered on the posterior pole, as equivalent to the clinical fundus examination through the slit lamp or indirect ophthalmoscopy for the assessment of SiO emulsion.

After the two rounds of discussion, the parameters to grade that reached the consensus were:

- Extent of SiO microbubbles on the retinal surface. Microbubbles of emulsified SiO can be seen as small creamy bubbles in SiO-filled eyes. All the experts agreed on the feasibility of a topographic quantification system using commonly used reference points. Unanimous consensus was reached on the detection of SiO microbubbles on three concentric zones corresponding to the posterior pole (zone 1), the area between the outer edge of zone 1 and the posterior edge of the vortex vein ampulla (zone 2) and the area between outer edge of zone 2 and ora serrata (zone 3). In zones 2 and 3, SiO emulsion is further quantified based on the extent in clock hours of occupied area by microbubbles (Table 1).

- Presence of large (>125 μm) SiO bubble(s), including subretinal bubbles. The cut-off of 125 μm, corresponding to the width of an average large vein at the edge of the optic disc, is commonly used in clinical practice.[8]

- Number of floating SiO emulsified microbubbles in the vitreous cavity, only after removal of SiO (ROSO). These microbubbles are most commonly seen in the upper part of the vitreous cavity when conventional SiO is used.

*SiO-associated hyperreflective (HR) dots detectable on macular optical coherence tomography (OCT)*

Macular OCT was unanimously considered a mandatory investigation to include in the grading system (100% of the expert scored between 8 and 9). Based on the reported locations of SiO-associated HR dots [9-11] in the macula, consensus was reached on a topographic quantification system differentiating HR dots located epiretinally, within the inner retinal layers (IRLs) or within the outer retinal layers (ORLs).

*SiO-associated HR dots detectable on OCT disc*

Non-unanimous consensus was reached on the inclusion of OCT of the optic disc (5 of 7 experts scored ≥ 7 and 2 experts scored 6). After the two rounds of discussion, agreement was achieved on a quantification of SiO-associated HR dots in two different locations, namely within the optic disc, and between the optic disc and SiO meniscus in SiO-filled eyes or within optic disc excavation after ROSO.

**Discussion**

Silicone oil emulsification is considered a major complication of SiO tamponade.[1,4,12]. Small oil droplets (emulsion) form by surface extension from the main SiO bubble and subsequent stabilization of these emulsified droplets, dispersed in the aqueous phase by reduction of their interfacial tension preventing their coalescence. Various emulsifiers, including biosurfactants (mainly lipids and proteins) and low molecular weight components, can contribute to this reduction in interfacial tension and stabilization of the emulsion.[13] Histopathological studies have demonstrated that emulsified SiO droplets can be detected within the cornea, trabecular meshwork, ciliary body, retina and optic nerve, supporting their ability to infiltrate ocular tissues and, also more importantly, their main pathogenetic role in SiO-related complications.[2,3] In addition, SiO microbubbles can be phagocytosed by retinal pigment epithelial cells, resident microglial cells and macrophages, potentially contributing to the development of SiO-related intraocular inflammation, that, in turn, further promotes SiO emulsification.[14]

Although SiO emulsion has been widely reported on clinical examination in all the ocular structures and is a feared complication of SiO tamponade, there is currently no standardized protocol to grade its extent. The absence of an agreed objective clinical grading system of SiO emulsion results in the impossibility to draw strong conclusions on the clinical relevance of emulsification and its pathogenetic role in SiO-related ocular complications. In addition, the availability of an easy and consistent method for quantifying SiO emulsion would provide an objective method of comparing SiO of differing purities, viscosities and compositions. Indeed, despite various SiO having been introduced with the specific aim of decreasing the rate of emulsification, their use is not supported by any clear clinical evidence.[1,15] Moreover, the collection of clinical information in a protocolized manner is one of the requirements of the Medical Devices Regulation implemented by the European Commission.

The evidence-based expert-led consensus aimed to fill this important gap proposing the first grading system of SiO emulsion (ITEMS grading system)to more reliably quantify the presence and extent of any SiO emulsion. In a healthcare context, the expert panel technique method is a validated methodology, commonly used to evaluate the appropriateness of clinical interventions and to identify measures for clinical studies.[6] It has also been suggested that this technique may be superior to the Delphi methodology for consensus.[16]

The expert group unanimously identified that the evaluation of the anterior segment through slit lamp examination was an essential investigation for the assessment of SiO emulsion. The presence of SiO emulsion in the AC is supposed to play a crucial role in SiO-associated corneal and intraocular pressure (IOP)-related complications.[1] Emulsified SiO droplets in the AC in contact with the corneal endothelium may contribute to SiO-related keratopathy.[1] A direct cytotoxic effect of both 5000 and 1000 mPa•s SiOs has been demonstrated on cultivated human corneal endothelial cells (CEC) [17]. Various corneal morphological and biomechanical changes have been associated with SiO tamponade and several studies have supported a positive correlation between the presence of clinically detectable SiO in the AC and a higher incidence of CEC loss [5]; however, the specific role of SiO emulsification has not been investigated and no characterization of the extent of SiO emulsion provided.[5] On the contrary, Goezinne et al. [18] reported no association between CEC loss and the degree of SiO emulsification; however, the methodology for assessing the extent of SiO emulsion was not specified.

Gonioscopy has been reported to show a higher rate of emulsification than slit lamp biomicroscopy alone.[19] Emulsified SiO droplets in the iridocorneal angle may have a primary role in the development of SiO-related ocular hypertension and glaucoma, through two different mechanisms, namely by triggering of trabeculitis and mechanical obstruction of the trabecular meshwork with consequent impairment of the aqueous humor outflow. [20] Consistently, the amount of angle SiO emulsion correlates with the rate of development of secondary glaucoma. [21] However, the detection of SiO droplets in the angle may not be necessarily associated with increased IOP, as suggested by Valone et al [22] who found SiO emulsion on gonioscopy in more than 50% of 48 SO-filled eyes, but only responsible for secondary glaucoma in 20%.

No classification is currently available for the evaluation of SiO emulsion on fundoscopy as well as any report or study differentiating the emulsified SiO bubbles detectable in the vitreous chamber or on the retinal surface based on their location. This is surprising as the vitreous cavity is filled with the main SiO bubble and, thus represents the primary site of emulsification. In addition, different detrimental effects of SiO, and SiO emulsion in contact with the retinal tissue, such as toxicity and SiO-induced inflammation, have been speculated as potential pathogenetic mechanisms of SiO-related retinal changes.[5,23-25]

Ultra-widefield photography is allowed in the grading system as an alternative or complementary to fundoscopy given its recognized reliability and widespread use for the assessment of retinal pathologies. [26,27]

There was unanimous consensus on the inclusion of macular OCT as part of the routine examinations to evaluate emulsion. Emulsified SiO droplets have been described as HR dots, variable in size and located both intraretinally and epiretinally, on OCT.[9-11] Whether these HR dots may represent SiO emulsified droplets that have migrated intraretinally [9] or phagocytosed by macrophages or microglial cells, has not been elucidated.[2] Various clinically relevant macular changes have been described in association with the use of SiO, in terms of both morphological alterations (cystoid macular edema (CME), epiretinal membrane (ERM), submacular fluid or fibrosis) and structural alterations of the retinal layers.[5] The potential association between SiO-related ERM and CME and the detection of emulsified SiO droplets has been previously reported.[5] In particular, SiO-related ERM appears to be characterized by the presence of SiO droplets, within both the ERM itself and the ERM-associated macrophages [2], whereas HR dots can be detected within macular cysts.[9] Microcystic macular changes caused by persistent SiO emulsion bubbles should not be confused with small hyper-reflective spherical bodies in the subretinal space which more likely are residual SiO globules with an incomplete septum among them, a feature that has been named the “caterpillar sign”, and casting a choroidal shadow at the borders of the bubbles.[28] In addition, SiO has been associated with macular thinning, mainly related to the reduced thickness of IRLs.[5]

The inclusion of disc OCT in the grading system was recommended as the detection and quantification of SiO emulsion at the optic nerve head may help in elucidating the role of emulsified SO in the pathogenesis of SiO-related optic neuropathy. Indeed, in this regard, a direct role of SiO emulsification has been hypothesized in terms of direct toxicity of SiO droplets after migration into the retrolaminar optic nerve.[29] Furthermore, detectable epi-papillary SiO droplets may be associated with the development of glaucoma.[11]

The novel concept of differentiating SiO microbubbles from larger SO bubbles is worth noting. Indeed, no characterization of the size of SiO bubbles has been reported except in a experimental setting, not applicable to clinical practice.[3] However, the evidence of the penetration of SiO microbubbles within ocular tissues as well as the ability of various cell types to phagocyte them, may support the greater harmful potential of SiO microbubbles compared to larger SiO bubbles.

In conclusion, we propose this consensus-based InTraocular EMulsion of Silicone oil (ITEMS) grading system as a widely and easily applicable tool, that will allow, for the first time, an objective assessment and comparison of SiO emulsification levels. It has the potential to clarify the correlation between SiO emulsification and clinical findings and, thus to improve our understanding of the pathogenesis of SiO-associated complications. With this aim, we also plan a future prospective study to validate the proposed grading system clinically to differentiate varying severities of SiO emulsification and correlate these with clinical signs.

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**Figure Legend**

**Figure 1.** Design of the consensus protocol for the development of the InTraocular EMulsion of Silicone oil grading system

**Table 2**. InTraocular EMulsion of Silicone oil (ITEMS) grading system – Score

|  |  |  |  |
| --- | --- | --- | --- |
| **Investigation** | **Parameter ± location** | **Measure** | **Score** |
| Slit Lamp Examination Anterior Segment | SiO emulsified microbubble (<200 μm) into AC(using 1x1 mm slit lamp beam in width and height)(to measure in the upper third of AC if conventional SO and lower third if HSO) | None | 0 |
| < 5 | 0.5 |
| 5-15 | 1 |
| 15-30 | 2 |
| > 30 | 3 |
| Large (>200 μm) SiO bubble(s) | None | 0 |
| Present | 1 |
| Hyperoleon (creaming)(to measure in the upper AC if conventional SO and lower AC if HSO) | None | 0 |
| < 1 mm | 2 |
| 1-3 mm | 4 |
| > 3mm | 6 |
| Gonioscopy | Extent of SiO microbubbles in the iridocorneal angle | None | 0 |
| < 90° | 2 |
| > 90° | 4 |
| Large SiO bubble(s) | None | 0 |
| Present | 1 |
| Dilated fundus examination (slit lamp or indirect ophthalmoscopy)**OR**UltraWide-field fundus photo(centered on the posterior pole) | Extent of SiO microbubbles(<125 μm)on the retinal surface | Posterior pole | None | 0 |
| Present | 3 |
| Mid- and far-peripheral retina | None | 0 |
| < 90° | 2 |
| > 90° | 4 |
| Large (>125 μm) SiO bubble(s), including subretinal | None | 0 |
| Present | 1 |
| Floating SO emulsified microbubble into vitreous cavity (only if after ROSO) | None | 0 |
| Present | 2 |
| OCT Macula(horizontal **OR** vertical line scans crossing the foveal centre) | SiO-associated HR dots | Epiretinal | None | 0 |
| Present | 1 |
| Intraretinal | None | 0 |
| Present | 3 |
| OCT optic disc(horizontal and vertical line scans crossing the optic disc center) | SiO-associated HR dots | Between optic disc and SiO meniscus (if SiO in situ) **OR** within optic disc excavation (if after ROSO) | None | 0 |
| Present | 1 |
| Within optic disc | None | 0 |
| Present | 3 |

AC, anterior chamber; HR, hyperreflective; HSO, heavy silicone oil; ROSO, removal of silicone oil; SiO, silicone oil